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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,140	07/19/2004	Jung Joon Lee	04-417	9176

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,140	LEE ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *July 19, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims Pending

Claims 1-10 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to prevention of hepatitis. The specification is not considered to enable this use. Applicant's specification does not give any examples that show that *Acanthopanax koreanum* is able to prevent hepatitis. "Prevention" of hepatitis requires prevention of each and every instances of hepatitis. Such prevention is difficult, if not impossible, to achieve. Hepatitis can be prevented by a vaccine or the numerous items listed (see http://health.allrefer.com/health/hepatitis-prevention.html). Applicant does not discuss the known means for preventing hepatitis. Thus, Applicant does not provide enough information for a person of ordinary skill in the art to determine without undue experimentation that *Acanthopanax koreanum* claimed is able to prevent hepatitis.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the water extract" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the treatment" in line 3. There is insufficient antecedent basis for this limitation in the claim.

In claim 1, it is not clear what Applicant is meaning in the term "protective." Clarification is needed.

In claim 2, it is not clear what Applicant is meaning in the recitation "among the said water extract." Does this mean the water extract with the ethanol part? Clarification is needed.

Claim 2 recites the limitation "the ethanol insoluble part" in line 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 3, it is not clear what Applicant is meaning in the recitation "among the said ethanol." What is "among"? Clarification is needed.

In claim 4, it is not clear what Applicant is meaning in the recitation "among the said ethanol." What is "among"? Clarification is needed.

Claims 3 and 4 recites the limitation "the fraction containing" in line 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 5, Applicant states "ethanol is in between 50 and 90%." It is unclear what the concentrations refer to. Is it the concentration of ethanol used or the concentration of the part in the total composition? Clarification is needed.

In claim 6, Applicant states "concentration of ethanol is 80%." It is unclear what the concentrations refer to. Is it the concentration of ethanol used or the concentration of the part in the total composition? Clarification is needed.

Claims 5-6 recites the limitation "the final concentration" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

In claims 7-10, the term "effective" is unclear because it is not understood what is encompassed with this term. Clarification is needed.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Palladino *et al.* (6,365,768).

Applicant's claims are drawn to product-by-process claims. The product is an extract from *Acanthopanax koreanum* stem or root. Regarding product-by-process claims, note that MPEP § 2113 states that:

> "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)."

Palladino *et al.* (6,365,768) teach using an extract of *Acanthopanax koreanum* to inhibit Tumor Necrosis Factor-α (i.e. TNF-α) which can be attributed to viral infections such as hepatitis viruses and cirrhosis (column 2, lines 4-5; column 14, lines 29-33; column 22, lines 19-37).

The reference does not specifically teach that the product is extracted using the method claimed by Applicant in claim 1 or that the extract contains all of the characteristics claimed in claims 2, 3 and 4. However, the reference product reasonably appears to be the same product as claimed because the reference product is extracted from the same source as claimed and has the same TNF-α (i.e. Tumor Necrosis Factor-α inhibitory activity and viral infection (i.e.hepatitis) is claimed.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidence by their shared TNF-α (i.e. Tumor Necrosis Factor- α inhibitory activity and viral infection (i.e. hepatitis).

Thus, the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pyun *et al.* (5,900,434).

Applicant's claims are drawn to product-by-process claims. The product is an extract from *Acanthopanax koreanum* stem or root. Regarding product-by-process claims, note that MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)."

Pyun *et al.* (5,900,434) teach using an extract of *Acanthopanax koreanum* to inhibit Tumor Necrosis Factor-α (i.e. TNF-α) which can be attributed to hepatocirrhosis (column 3, lines 41-55; column 4, lines 4-11).

The reference does not specifically teach that the product is extracted using the method claimed by Applicant in claim 1 or that the extract contains all of the characteristics claimed in claims 2, 3 and 4. However, the reference product reasonably appears to be the same product as claimed because the reference product is extracted from the same source as claimed and has the same TNF-α (i.e. Tumor Necrosis Factor-α inhibitory activity and viral infection (i.e.hepatitis)) is claimed.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidence by their shared TNF-α (i.e. Tumor Necrosis Factor- α inhibitory activity and viral infection (i.e. hepatitis)).

Thus, the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suh *et al.* (US 6,593,363) in view of Eloff ("Which extractant should be used for the screening and

isolation of antimicrobial components from plants?" Journal of Ethnopharmacology, 60, (1998) pages 1-8).

Suh *et al.* (US 6,593,363) discloses extracting *Acanthopanax koreanum* with water and an alcohol. Suh *et al.* does not disclose extracting specifically with ethanol.

Eloff ("Which extractant should be used for the screening and isolation of antimicrobial components from plants?") discloses that there are numerous extractants (such as methanol or ethanol or acetone, etc.) that can be used for extracting plant metabolites.

It would be obvious to substitute ethanol for methanol because they are both known in the art to have similar solvent characteristics. One of ordinary skill in the art would reasonably expect to use ethanol in Suh *et al.* because of the lower toxicity in ethanol than in methanol as shown in Eloff. Based on this reasonable expectation of success, one of ordinary skill in the art would be motivated to substitute ethanol for methanol in extracting *Acanthopanax koreanum.*

Summary

No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
10-25-05
SUSAN COE
PRIMARY EXAMINER